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10/510,321

05/25/2005

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6886

270 7590 05/12/2008

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EXAMINER

GUSSOW, ANNE

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,321	<b>Applicant(s)</b> DIAMANDIS ET AL.	
	<b>Examiner</b> ANNE M. GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10, 14-23, 25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 14-23, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/4/04, 3/9/06</u> .                                         | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group I, claims 1-6, 10, 14-23, 25, and 27, and the species of CA125 in claim 17, in the reply filed on March 24, 2008 is acknowledged.

2. Claims 16 and 27 have been amended.

Claims 7-9, 11-13, 24, 26, and 28-29 have been cancelled.

3. Claims 1-6, 10, 14-23, 25, and 27 are under examination.

### ***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on October 4, 2004 and March 9, 2006 have been fully considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Objections***

6. Claims 6 and 10 are objected to because of the following informalities: the claims contain typographical errors. In claim 6 line 1 “aggressiveness of indolence” should read “aggressiveness or indolence” and in claim 10 line 8, “in an indication” should read “is an indication”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite for reciting the phrase “aggressiveness of indolence”. It is not clear which characteristic the claim is measuring, aggressiveness of the tumor or indolence of the tumor. The specification does not define the terms aggressiveness or indolence. Stedman’s Medical Dictionary (27<sup>th</sup> edition, 2000. online version) defines aggressiveness as denoting a competitive forcefulness or invasiveness and indolence as inactive or sluggish. Thus, the terms appear to be opposites of each other. As claimed, it is not clear which quality is being detected by the significant difference between the levels in patient samples and the normal levels.

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9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 5 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting ovarian cancer or ovarian cancer metastasis in a patient, does not reasonably provide enablement for determining a predisposition to ovarian cancer or the likelihood of future metastasis of ovarian cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988).

Wands states on page 1404,  
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are broadly drawn to a method for determining in a patient whether ovarian cancer has metastasized or is likely to metastasize in the future, the method comprising comparing (a) levels of a kallikrein 8 polypeptide in a patient sample; and (b) normal levels or non-metastatic levels of a kallikrein 8 polypeptide, in a control

sample wherein a significant difference between levels of expression in the patient sample and the normal levels or non-metastatic levels is an indication that the ovarian cancer has metastasized. A method in an electronic system and/or in a network for determining whether a subject has ovarian cancer or a pre-disposition to ovarian cancer associated with a kallikrein 8 polypeptide comprising (a) determining the presence or absence of a kallikrein 8 polypeptide, and (b) based on the presence or absence of the kallikrein 8 polypeptide, determining whether the subject has ovarian cancer or a pre-disposition to ovarian cancer, and (c) optionally recommending treatment for the ovarian cancer or pre-ovarian cancer condition.

The specification discloses detection of kallikrein 8 at increased levels in patients with metastatic ovarian cancer. The specification discloses detection of kallikrein 8 in a number of tissue samples and cancer cell lines. The specification does not disclose a correlation between the level of kallikrein 8 in a patient sample and a future ovarian cancer or metastatic ovarian cancer. The specification does not provide any teachings of the broadly claimed predisposition to ovarian cancer, how to determine the individuals who will develop ovarian cancer, nor does the specification teach how to predict when a cancer would occur in any individual or the optimal time before such a occurrence to detect the kallikrein 8 of the instant invention. Thus, one of skill in the art would not be able to use the method of the invention without undertaking to determine how to select for individuals who will develop ovarian cancer before the cancer occurs in the individual.

Baker and Kaprio (British Medical Journal, 2006. Vol. 332, pages 1150-1152)

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teach that cancer susceptibility genes are unlikely to exist or if they do exist are unlikely to have much of an effect on the incidence of cancer (page 1151). Baker and Kaprio go on to define several reasons to support their argument including that early phases of carcinogenesis involve alterations in stroma (supporting tissue) rather than parenchyma (functional tissue), migration studies suggest external changes have a large effect on the incidence of cancer, and studies of cancer in twins showed that genetic susceptibility made only a small contribution to the incidence of cancer (page 1151). Janssens, et al. (European Journal of Cancer Prevention, 2004. Vol. 13, pages 307-317) teach that the ideal tumor risk biomarker for cancer prevention is different from prognostically useful molecules in that it should be a molecule that is expressed very early at the origin of the disease and that a combination of many differentially expressed proteins or profiles might be more useful (page 307).

In view of the lack of predictability of the art to which the invention pertains, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for determining predisposition or susceptibility to metastatic ovarian cancer, commensurate in scope with the claimed invention.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3, 5, 6, 14-16, 22, 23, 25, and 27 are rejected under 35 U.S.C. 102(a,e) as being anticipated by O'Brien, et al. (U.S. PG PUB 2002/0037581, published March 28, 2002, filed February 28, 2001), as evidenced by the specification.

The claims recite a method for detecting a kallikrein 8 polypeptide associated with ovarian cancer in a patient comprising: (a) obtaining a sample from a patient; (b) detecting in the sample kallikrein 8 polypeptide; and (c) comparing the detected amounts with amounts detected for a standard, wherein the patient sample comprises serum obtained from the patient, wherein the kallikrein 8 polypeptide is detected using antibodies that bind to a kallikrein 8 polypeptide or part thereof, wherein the antibodies are used in an immunoassay. A method for diagnosing and monitoring ovarian cancer in a subject comprising detecting in a sample from the subject a kallikrein 8 polypeptide. A method of detecting ovarian cancer in a patient, the method comprising comparing:



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(a) levels of a kallikrein 8 polypeptide in a sample from the patient; and (b) normal levels of expression of kallikrein 8 polypeptide in a control sample, wherein a significant difference in the levels of kallikrein 8 polypeptides, relative to the corresponding normal levels, is indicative of ovarian cancer. A method for determining in a patient whether ovarian cancer has metastasized or is likely to metastasize in the future, the method comprising comparing (a) levels of a kallikrein 8 polypeptide in a patient sample; and (b) normal levels or non-metastatic levels of a kallikrein 8 polypeptide, in a control sample wherein a significant difference between levels of expression in the patient sample and the normal levels or non-metastatic levels is an indication that the ovarian cancer has metastasized. A method for assessing the aggressiveness or indolence of ovarian cancer comprising comparing: (a) levels of expression of a kallikrein 8 polypeptide in a patient sample and (b) normal levels of expression of the kallikrein 8 polypeptide, in a control sample, wherein a significant difference between the levels in the patient sample and normal levels is an indication that the cancer is aggressive or indolent. A kit for assessing whether a patient is afflicted with ovarian cancer, the kit comprising reagents that specifically bind with kallikrein 8 polypeptides, wherein the reagents are antibodies that specifically bind with protein or protein fragments corresponding to a kallikrein 8 polypeptide. A method in an electronic system and/or in a network for determining whether a subject has ovarian cancer or a pre-disposition to ovarian cancer associated with a kallikrein 8 polypeptide comprising (a) determining the presence or absence of a kallikrein 8 polypeptide, and (b) based on the presence or absence of the kallikrein 8 polypeptide, determining whether the subject has ovarian cancer or a pre-disposition to

ovarian cancer, and (c) optionally recommending treatment for the ovarian cancer or pre-ovarian cancer condition.

O'Brien, et al. teach detection of TADG-14 protein using an anti-TADG-14 antibody in an immunoassay. O'Brien, et al. teach the steps of obtaining a sample from a patient, including cells, blood, plasma, or tissue for detection of TADG-14 protein in an immunoassay such as an ELISA to detect or diagnose ovarian cancer (page 6 paragraph 70). O'Brien, et al teach that no staining was detected in normal ovarian tissue samples but intense staining was detected in several subtypes of ovarian carcinoma (page 9 paragraph 101). O'Brien, et al. teach the amino acid sequence of TADG-14 is identical to the amino acid sequence of neuropsin (page 9 paragraph 97). Neuropsin is a synonym for kallikrein 8 as evidenced by the specification (see pg. 1). O'Brien, et al. also teach a kit for detecting TADG-14 protein comprising an antibody specific for TADG-14 and the means to detect the antibody (claims 21-22). Since the active steps in each of the claimed methods are obtaining a sample from a patient and detecting kallikrein 8 and O'Brien et al. teach obtaining a sample from a patient and detecting TADG-14 which is identical to kallikrein 8, the detection of TADG-14 would also detect kallikrein 8 and all the limitations of the claims have been met.

13. Claims 1-3, 5, 6, 15, 16, 23, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Underwood, et al. (Cancer Research, 1999. Vol. 59, pages 4435-4439, as cited on the IDS), as evidenced by the specification.

The claims have been described supra.

Underwood, et al. teach detection of TADG-14 protein in an immunoassay using an anti-TADG-14 antibody. Underwood, et al. teach no detection in normal ovarian tissues and intense staining for TADG-14 in different subtypes of ovarian carcinoma (figure 5). Underwood, et al. teach the protein of TADG-14 is identical to the neuropsin protein (page 4438 1st column). Neuropsin is a synonym for kallikrein 8 as evidenced by the specification (see pg. 1). Since the active steps in each of the claimed methods are obtaining a sample from a patient and detecting kallikrein 8 and Underwood et al. teach obtaining a sample from a patient and detecting TADG-14 which is identical to kallikrein 8, the detection of TADG-14 would also detect kallikrein 8 and all the limitations of the claims have been met.

14. Claims 1-3, 5, 6, 14-16, 18-21, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Brien, et al. (US PAT 6,642,013, filed July 18, 2000), as evidenced by the specification.

Claims 1-3, 5, 6, 14-16, and 27 have been described supra. Claims 18-21 recite a method for screening a subject for ovarian cancer comprising: (a) incubating a biological sample from the subject with a first antibody specific for hK8 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for hK8 which is immobilized; (b) separating the first antibody from the second antibody to provide a first antibody phase and a second antibody phase; (c) detecting the detectable substance in the first or second antibody phase thereby quantitating hK8 in the biological sample; and (d) comparing the quantitated hK8 with levels for a

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predetermined standard. An in vivo method for imaging ovarian cancer comprising: (a) injecting a patient with an agent that binds to a kallikrein 8 polypeptide, the agent carrying a label for imaging the ovarian cancer; (b) allowing the agent to incubate in vivo and bind to a kallikrein 8 polypeptide associated with the ovarian cancer; and (c) detecting the presence of the label localized to the ovarian cancer, wherein the agent is an antibody which recognizes a kallikrein 8 polypeptide, wherein the label is a radiolabel, fluorescent label, nuclear magnetic resonance active label, positron emitting isotope detectable by a positron emission tomography ("PET") scanner, chemiluminescer, or enzymatic marker.

O'Brien, et al. teach detection of TADG-14 protein using an anti-TADG-14 antibody in an immunoassay. O'Brien, et al. teach the steps of obtaining a sample from a patient, including cells, blood, plasma, or tissue for detection of TADG-14 protein in an immunoassay such as an ELISA to detect or diagnose ovarian cancer (column 11 lines 26-48). One of ordinary skill in the art would recognize that an ELISA comprises a first antibody phase and a second antibody phase, wherein one antibody would be immobilized on a support for detecting the protein of interest as specified in claim 18. O'Brien, et al teach that no staining was detected in normal ovarian tissue samples but intense staining was detected in several subtypes of ovarian carcinoma (column 17 lines 13-19). O'Brien, et al. teach the amino acid sequence of TADG-14 is identical to the amino acid sequence of neuropsin (column 16 lines 4-8). Neuropsin is a synonym for kallikrein 8 as evidenced by the specification (see pg 1). O'Brien, et al. also teach the antibody can be conjugated to a detectable label for in vivo diagnostic such as

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magnetic resonance imaging (column 10 lines 40-68). Since the active steps in each of the claimed methods are obtaining a sample from a patient and detecting kallikrein 8 and O'Brien et al. teach obtaining a sample from a patient and detecting TADG-14 which is identical to kallikrein 8, the detection of TADG-14 would also detect kallikrein 8 and all the limitations of the claims have been met.

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1-6, 10, 14-17, 22, 23, 25, 27 rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien, et al. (US PG PUB 2002/0037581 filed February 28, 2001) in view of Lee et al. (US PG PUB 2003/0165831, filed March 21, 2001).

Claims 1-3, 5, 6, 14-16, 22, 23, 25, and 27 have been described supra. Claims 4, 10, 17 recite a method for monitoring the progression of ovarian cancer in a patient, the method comprising: (a) detecting in a sample from the patient at a first time point, a kallikrein 8 polypeptide; (b) repeating step (a) at a subsequent point in time; and (c) comparing levels detected in steps (a) and (b), and thereby monitoring the progression of ovarian cancer. A method of assessing the efficacy of a therapy for inhibiting ovarian cancer in a patient, the method comprising comparing; (a) levels of a kallikrein 8 polypeptide in a first sample obtained from the patient, and (b) levels of the kallikrein 8 polypeptide in a second sample obtained from the patient following therapy, wherein a significant difference in the levels of expression of the kallikrein 8 polypeptide in the second sample relative to the first sample, is an indication that the therapy is efficacious for inhibiting ovarian cancer in the patient. A method as claimed in claim 1 which further comprises detecting CA125.

O'Brien, et al. has been described supra. O'Brien et al teach detection of TADG-14 (kallikrein 8) using an anti-TADG-14 antibody in a patient sample to detect ovarian cancer. O'Brien et al. do not teach detection of kallikrein 8 to monitor the progression of ovarian cancer. O'Brien et al. do not teach detection of CA125 in addition to kallikrein 8. These deficiencies are made up for in the teachings of Lee, et al.

Lee, et al. teach detection of a plurality of markers to detect ovarian cancer, monitor the progression of ovarian cancer, and monitor the efficacy of treatment for ovarian cancer comprising a) detecting in a patient sample at a first time point, the expression of a marker b) repeating step a) at a subsequent time point in time; and c) comparing the level of expression detected in steps a) and b), and therefrom monitoring the progression of ovarian cancer in the patient (page 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have detected by detecting kallikrein 8 as taught by O'Brien, et al. and monitored the progression of ovarian cancer in view of Lee, et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have detected kallikrein 8 and CA125 to detect breast cancer as taught by O'Brien et al. and monitor the progression of ovarian cancer as taught by Lee, et al. because O'Brien, et al. teach that CA125 was the best available ovarian cancer tumor marker as of February 21, 2001 but high endogenous circulating levels of CA125 limit its usefulness as a diagnostic tool (page 10 paragraph105) and Lee, et al teach that CA125 does not exhibit sufficient specificity for use as a general

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screening method and is associated with conditions other than ovarian cancer (page 2 paragraph 11). Regarding the monitoring of ovarian cancer progression and efficacy of chemotherapy, Lee, et al. teach repeated monitoring of cancer markers in patient samples over a period of time. Since O'Brien, et al. teach detection of kallikrein 8 at a single time point to detect ovarian cancer, one of ordinary skill in the art would identify kallikrein 8 as an ovarian cancer marker and be able to use the method steps of Lee, et al. to monitor ovarian cancer over time. Additionally, Lee, et al. teach detection of kallikrein 8 at different time points to monitor cancer progression (paragraphs 37-40) and for monitoring the effectiveness of cancer treatment (paragraph 304). Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have detected kallikrein 8 and CA125 to detect ovarian cancer as taught by O'Brien, et al. and monitor the progression of ovarian cancer in view of Lee, et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Conclusion***

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is



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(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

May 7, 2008

/David J Blanchard/  
Primary Examiner, Art Unit 1643